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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/250,657	05/27/1994	PAUL J. MULHAUSER	B02217061	1585

7590 12/04/2003

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/04/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/250,657

Applicant(s)

MULHAUSER ET AL. *ch*

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48-64 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48,60-64 and 73-76 is/are rejected.
- 7) ☒ Claim(s) 49-59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48,60-64,73-76 are rejected under 35 U.S.C. 112, first paragraph, because the written description of the specification defines the "loading and delivery" device as the combination of the main body and the cartridge and the claim recites only the main body of the combination. The specification does not support the invention as claimed.

The preamble of the claims is directed to an "apparatus for loading and delivering" a prosthesis. Interpreting the preamble in view of the specification, the elements required to meet the functions of the apparatus would include the main body, the introducer shaft and the cartridge. As broadly worded, the claims are incomplete since all elements of the apparatus are not positively set forth.

In the specification, pages 18 and the "loading and delivery" instrument is defined as an apparatus including the main body 202, the introducer shaft 206, and the

cartridge 210. Moreover, on page 19, the specification sets forth elements located in the cartridge that function to align the implant with the opening in the main body.

In the specification, the only example describing the working of the "loading and delivery" apparatus is found on page 22. The specification describes the function of loading and delivery as placing the distal end of the main body into a trocar, rotating the introducer shaft that draws the expanded implant from the cartridge into the main body lumen. The specification clearly sets forth applicant's invention of a "loading and delivery" apparatus as comprising three elements, the main body, the introducer and the cartridge. Accordingly, every element of the apparatus that is required for the functions of "loading and delivery" must be set forth in the claims.

#### ***Allowable Subject Matter***

Claims 49-59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed November 19, 2003 have been fully considered but they are not persuasive. Applicant's argues that an identical set of claims and a nearly identical set of claims had been previously allowed. And due to history the claims have passed several examinations. This argument has no relevance in overcoming the


outstanding rejections. Applicant argues that the claims are definite in that they do particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Moreover, applicant argues that one of ordinary skill in the art would readily understand the scope of the claims based on the description of a "loading and delivering apparatus" contained in the specification and the illustration of a "loading and delivering apparatus" provided in the drawings. Applicant argues that the specification and the drawings support the loading and delivery apparatus as broadly claimed. Applicant states that the "cartridge" is a feature of an embodiment of a loading and delivery apparatus. This statement is not clearly supported by applicant's disclosure. The preamble of the claims is directed to an apparatus for "loading and delivery" a prosthesis, yet the only element set forth in the claim is the main body. The specification discloses only one embodiment of the "loading and delivery apparatus" and not "an embodiment" of a plurality of embodiments. According to the specification, the loading and delivery apparatus (200) include main body (202), introducer shaft (206) and cartridge (210). The specification fails to disclose any other embodiments directed to an alternative means for loading the mesh to the inserter. The specification is specific to workings of the combination of the cartridge and the inserter tool. Therefore the claims as presented are incomplete.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
DECEMBER 1, 2003